



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0093; FRL-9906-17]

N-(n-octyl)-2-pyrrolidone; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687-94-7) when used as an inert ingredient (solvent) in formulations of pyraflufen-ethyl herbicide at a maximum concentration of 20% weight. Wagner Regulatory Associates on behalf of Nichino America, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of N-(n-octyl)-2-pyrrolidone.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0093, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the

Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0093 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0093, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL-9380-2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-10541) by Nichino America, Inc. 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR 180.1130 be amended by establishing an exemption from the requirement of a tolerance for residues of N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687-94-7) when used as an inert ingredient (solvent) in formulations of pyraflufen-ethyl herbicide at a maximum concentration of 20% weight. That document referenced a summary of the petition prepared by Wagner Regulatory Associates, Inc. 7217 Lancaster Pike, Suite A, P.O. Box 640, Hockessin, Delaware 19707, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in

establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for N-(n-octyl)-2-pyrrolidone including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with N-(n-octyl)-2-pyrrolidone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by N-(n-octyl)-2-pyrrolidone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Based on the results of acute toxicity studies in rats, N- (n-octyl)-2-pyrrolidone is classified as having low acute toxicity via the oral and dermal routes of exposure. It is a dermal irritant and a dermal sensitizer.

In mammals, the primary target is the liver. In subchronic feeding studies in rats and dogs, N- (n-octyl)-2-pyrrolidone generally caused increases in both absolute and relative liver weights along with reduction in body weight gain/food consumption and changes in hematological and biochemical parameters. No chronic toxicity study is available.

In a developmental toxicity study in rats with N- (n-octyl)-2-pyrrolidone, there was no evidence of increased susceptibility in fetuses as toxic effects were observed only at the highest dose tested, 800 milligrams/kilograms/day (mg/kg/day), in which dams exhibited ruffled fur, ventral recumbency, somnolence, apathy, dyspnea and comatose state. Other adverse effects observed were a reduction in food consumption and slight body weight loss during the first days of dosing and reduced corrected body weight gain.

Developmental effects such as reduced body weight and delay in skeletal ossification were observed only in the presence of maternal toxicity. No reproductive toxicity, immunotoxicity or neurotoxicity data are available for N-(n-octyl)-2-pyrrolidone,

There were three genotoxicity studies available in the database for N-(n-octyl)-2-pyrrolidone. An Ames test, a mouse lymphoma assay and a mouse micronucleus test all showed negative results for genotoxicity of N-(n-octyl)-2-pyrrolidone.

No carcinogenicity studies were available in the database for N-(n-octyl)-2-pyrrolidone. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts for potential carcinogenicity for N-(n-octyl)-2-pyrrolidone. No structural alerts for carcinogenicity were identified for N-(n-octyl)-2-pyrrolidone. In the absence of any structural alerts and lack of mutagenicity concerns, N-(n-octyl)-2-pyrrolidone is not expected to be carcinogenic.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a

population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for N-(n-octyl)-2-pyrrolidone used for human risk assessment is given below:

1. *Acute dietary (all populations)*. There were no adverse effects observed attributable to a single dose for the general population (including infants and children) or females 13-49 years of age.
2. *Chronic dietary (all populations)*. The chronic population adjusted dose (cPAD) was established based on the NOAEL (30 mg/kg/day) from a 90-day oral toxicity study in dogs. The adverse effects seen in this study were several statistically significant changes in hematology and clinical chemistry parameters and statistically significant dose-related increases in both absolute and relative liver weights at the LOAEL of 90 mg/kg/day. A Food Quality Protection Act (FQPA) safety factor/database uncertainty factor of 3X is utilized for dietary risk assessment.
3. *Dermal, short-term (1-30 days)*. The level of concern (LOC) for short-term dermal exposure is a Margin of Exposure (MOE) of 300 between estimated human exposure and the NOAEL (30 mg/kg/day) from the 90-day oral toxicity study in dogs. An

FQPA safety factor/database uncertainty factor of 3X is utilized for dermal, short-term, assessment.

4. *Inhalation, short-term (1-30 days)*. The level of concern (LOC) for short-term inhalation exposure is a MOE of 300 between estimated human exposure and the NOAEL (30 mg/kg/day) from the 90-day oral toxicity study in dogs. An FQPA safety factor/database uncertainty factor of 3X for the short-term inhalation assessment.

Quantification of cancer risk is not appropriate since there are no concerns for cancer based on SAR analysis of N-(n-octyl)-2-pyrrolidone.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to N-(n-octyl)-2-pyrrolidone, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from N-(n-octyl)-2-pyrrolidone in food as follows:

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model/Food Commodity Intake Database (DEEM-FCID)TM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for N-(n-octyl)-2-pyrrolidone. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A

complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled “Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.” (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738.

In the case of N-(n-octyl)-2-pyrrolidone, EPA made specific adjustments to the dietary exposure assessment to account for the use limitations of N-(n-octyl)-2-pyrrolidone as an inert ingredient in cotton defoliant formulations containing thidiazuron and diuron as active ingredients as well as the proposed use as an inert ingredient in formulations of pyraflufen ethyl herbicide at a maximum concentration of 20% weight.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for N-(n-octyl)-2-pyrrolidone, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

The proposed use of N-(n-octyl)-2-pyrrolidone is as an inert ingredient in pyraflufen ethyl formulations which have uses resulting in potential residential

exposures. A screening level residential exposure and risk assessment was conducted based on the use pattern and application rates of pyraflufen ethyl products.

EPA assessed residential exposure using the following assumptions: All residential exposures are considered short-term in duration. The residential handler assessment included short-term exposures via the dermal and inhalation routes from treating golf courses, ornamental turf lawns, road sides, parks and sports fields. In terms of post-application exposure, there is the potential for dermal post- application exposure for individuals as result of being in an environment that has been previously treated with N-(n-octyl)-2-pyrrolidone. Short-term dermal exposures were assessed for adults, children 1-2 and adult/child golfer. The scenarios used in the aggregate assessment were those that resulted in the highest exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found N-(n-octyl)-2-pyrrolidone to share a common mechanism of toxicity with any other substances, and N-(n-octyl)-2-pyrrolidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that N-(n-octyl)-2-pyrrolidone does not have a common mechanism of toxicity with other substances. For information regarding

EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased susceptibility was seen in the developmental toxicity study on N-(n-octyl)-2-pyrrolidone. The maternal and developmental toxicity NOAEL was 200 mg/kg bw/day based on reduced body weight gain in dams and mean fetal body weight and delay in skeletal ossification at the LOAEL of 800 mg/kg bw/day. No reproductive toxicity study is available N-(n-octyl)-2-pyrrolidone.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3X for all scenarios. That decision is based on the following findings:

i. The toxicity database for N-(n-octyl)-2-pyrrolidone consists of 90-day oral toxicity studies in rats and dogs, several mutagenicity studies and a developmental

toxicity study. While there are no reproductive, neurotoxicity and chronic toxicity studies for N-(n-octyl)-2-pyrrolidone, there is no evidence of effects on reproductive parameters or of any effects suggestive of neurotoxicity from the available subchronic studies. Additionally, the most sensitive endpoint selected seen in the 90-day dog oral toxicity study is based on hematological and clinical chemistry parameters; increases in both absolute and relative liver weights; and reduction in body weight gain/food consumption—effects which are not expected to be progressive and for which the resultant exposure assessment is likely to be protective of chronic effects and characterize toxicity potential of N-(n-octyl)-2-pyrrolidone. Although additional data are unlikely to indicate more sensitive effects, EPA has retained a FQPA factor of 3X as a database uncertainty factor. No inhalation toxicity studies were available in the database; however, the only potential inhalation exposure to N-(n-octyl)-2-pyrrolidone is to pesticide applicators, and, even assuming that such exposure has some relevance to decisions on the FQPA safety factor, the inhalation exposure to N-(n-octyl)-2-pyrrolidone is negligible in comparison to exposure under other pathways. In these circumstances, neither retention or removal of the FQPA safety factor would have a meaningful impact on assessment of risk from inhalation exposure.

ii. No evidence of immunotoxicity was observed in the available database. Slight change in the clinical pathological parameters (decreases in albumin/globulin ratio and globulin levels) were not considered as an indication of an immunotoxic response since no effects on blood lymphocytes and no adverse findings in the spleen and thymus. Therefore, an immunotoxicity study is not required.

iii. There are no residual uncertainties identified in the exposure databases. As described earlier, EPA used worst case assumptions for the dietary food exposure assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to N-(n-octyl)-2-pyrrolidone in drinking water. EPA used similarly conservative assumptions to assess residential post application exposure of children as well as incidental oral exposure of children 1-2. These assessments will not underestimate the exposure and risks posed by N-(n-octyl)-2-pyrrolidone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, N-(n-octyl)-2-pyrrolidone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to N-(n-octyl)-2-pyrrolidone from

food and water will utilize 59.37% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. The chronic dietary exposure estimates for the total U.S. population was 14.31%.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). N-(n-octyl)-2-pyrrolidone is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to N-(n-octyl)-2-pyrrolidone.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,122 for adults and 291 for children 1-2. EPA's level of concern for N-(n-octyl)-2-pyrrolidone is a MOE of 300 or below, however these MOEs are not of concern based on the highly conservative assumptions made regarding residential and dietary exposures to N-(n-octyl)-2-pyrrolidone.

4. *Intermediate-term risk.* Intermediate-term residential aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyraflufen ethyl is not currently registered for uses that could result in intermediate-term residential exposure so an intermediate term risk assessment for N-(n-octyl)-2-pyrrolidone was not performed. There are also no intermediate-term adverse effects identified and therefore N-(n-octyl)-2-pyrrolidone is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* N-(n-octyl)-2-pyrrolidone is not expected to be carcinogenic.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to N-(n-octyl)-2-pyrrolidone residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of N-(n-octyl)-2-pyrrolidone in or on any food commodities. EPA is establishing a limitation on the amount of N-(n-octyl)-2-pyrrolidone that may be used in pesticide formulations.

The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any pesticide for sale or distribution containing pyraflufen ethyl as an active ingredient with concentrations of N-(n-octyl)-2-pyrrolidone exceeding 20% by weight of the pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is

recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for N-(n-octyl)-2-pyrrolidone.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.1130 for N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687-94-7) when used as an inert ingredient (solvent) in formulations of pyraflufen-ethyl herbicide at a maximum concentration of 20% by weight.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under

Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 18, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise §180.1130 to read as follows:

§ 180.1130 *N*-(*n*-octyl)-2-pyrrolidone and *N*-(*n*-dodecyl)-2-pyrrolidone; exemptions from the requirement of a tolerance.

(a) *N*-(*n*-octyl)-2-pyrrolidone and *N*-(*n*-dodecyl)-2-pyrrolidone are exempt from the requirement of a tolerance when used as solvents in cotton defoliant formulations containing thidiazuron and diuron as active ingredients.

(b) *N*-(*n*-octyl)-2-pyrrolidone is exempt from the requirement of a tolerance when used as a solvent in formulations containing pyraflufen-ethyl as an active ingredient at a concentration not to exceed 20% by weight.